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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,753	06/27/2003	Karl-Heinz Bozung	01-1088-3-C2	7182

28519 7590 10/09/2009

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EXAMINER
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KARPINSKI, LUKE E

ART UNIT	PAPER NUMBER
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1616

NOTIFICATION DATE	DELIVERY MODE
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10/09/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO.e-Office.rdg@boehringer-ingelheim.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/608,753	<b>Applicant(s)</b> BOZUNG ET AL.	
	<b>Examiner</b> LUKE E. KARPINSKI	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,5-7,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5-7, 9, and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

Receipt of amendments, arguments, and remarks filed 6/23/2009 is acknowledged.

### ***Claims***

Claims 2-4, 8, and 11-14 are canceled.

Claims 1, 6, 7, 9, and 10 are amended.

Claims 1, 5-7, 9, and 10 are currently pending and under consideration in this action.

### ***Rejections***

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***New Rejections***

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**1. Claims 1, 5, 7, 9, and 10 are rejected under 35 U.S.C. 103(a)** as being unpatentable over US Patent 5,612,053 to Baichwal et al.

### ***Applicant Claims***

Applicant claims are delineated above and incorporated herein.

***Determination of the Scope and Content of the Prior Art***

***(MPEP §2141.01)***

Baichwal et al. teach inhalable formulations comprising glycopyrrolate as an anticholinergic and salmeterol as a bronchodilator (col. 10, lines 1-46). Glycopyrrolate is a synonym for glycopyrronium bromide as evidenced by US Patent 6,645,466 to Keller et al. (col. 6, lines 52-67).

Baichwal et al. also teach carriers (col. 5, lines 53-59), as pertaining to claim 10.

***Ascertainment of the Difference between Scope the Prior Art and the Claims***  
***(MPEP §2141.012)***

Baichwal et al. do not explicitly disclose an example wherein the claimed components are combined into a single composition. However, Baichwal et al. do teach that said components may be combined into an inhalable formulation.

***Finding of prima facie Obviousness Rational and Motivation***

***(MPEP 2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to select each component and combine them as instantly claimed because Baichwal et al. suggests that the instant components can be combined or mixed together. In a prior art reference it is not necessary for all of the possible compositions to be exemplified in order for the art to render an invention obvious.

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Regarding claim 10, Baichwal et al. teach compositions comprising all of said components and said components must inherently be mixed together to form said formulations.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**2. Claims 1, 5, 7, 9, and 10 are rejected under 35 U.S.C. 103(a)** as being unpatentable over “How to effectively control your patient's dyspnea COPD management: Achieving bronchodilation to Gross, in view of US Patent 5,612,053 to Baichwal et al.

### ***Applicant Claims***

Applicant claims a composition comprising glycopyrronium bromide and a betamimetic selected from the list recited in instant claim 1.

Applicant further claims said betamimetic as formoterol or salmeterol, and said compositions as inhaled pharmaceuticals.

### ***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

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Gross teaches inhalable compositions comprising anticholinergics and beta agonists (page 183) as pertaining to claims 1, 5, 7, 9, and 10.

Gross further teaches salmeterol as said beta-agonist (page 186, table) as pertaining to claims 1, 5, 7, 9, and 10.

***Ascertainment of the Difference between Scope the Prior Art and the Claims  
(MPEP §2141.012)***

Gross does not teach glycopyrronium bromide as said anticholinergic as claimed in claim 1. This deficiency in Gross is cured by Baichwal et al. Baichwal et al. teach inhalation formulations comprising glycopyrrolate as an anticholinergic and salmeterol as a bronchodilator (col. 10, lines 1-46).

Gross also does not teach said formulations produced with a carrier material as claimed in claim 10. This deficiency in Gross is cured by Baichwal et al. Baichwal et al. teach inhalable formulations comprising carrier materials (col. 5, lines 54-59).

***Finding of Prima Facie Obviousness Rational and Motivation  
(MPEP §2142-2143)***

Regarding claims 1, 5-7, 9, and 10, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Gross with glycopyrrolate as taught by Baichwal et al. in order to produce the invention of instant claims 1, 5-7, 9, and 10.

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One of ordinary skill in the art would have been motivated to do this because Gross and Baichwal et al. both teach to inhalable formulations comprising anticholinergics and bronchodilators and Baichwal et al. teach specific compounds which may be utilized. Therefore it would have been obvious to utilize the glycopyrrolate of Baichwal et al., in the formulations of Gross in order to produce an inhalable formulation with known components.

Regarding claim 10, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Gross with a carrier material as taught by Baichwal et al. in order to produce the invention of instant claim 10.

One of ordinary skill in the art would have been motivated to do this because Gross and Baichwal et al. both teach inhalable formulations and Baichwal et al. teach that said formulations commonly comprise carrier materials. Therefore it would have been obvious to utilize the carriers of Baichwal et al., in the formulations of Gross in order to produce an inhalable formulation with known components.

Regarding the process of claim 10, Baichwal et al. teach compositions comprising all of said components and said components were inherently mixed together to form said formulations.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to



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one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**3. Claims 1, 5-7, 9, and 10 are rejected under 35 U.S.C. 103(a)** as being unpatentable over “Bronchodilators in the therapy of chronic obstructive pulmonary disease” to Rees, in view of US Patent 5,612,053 to Baichwal et al.

***Applicant Claims***

Applicant claims are delineated above and incorporated herein.

***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

Rees teaches the combination of beta-agonists and anticholinergics in inhalable formulations (page 137, last paragraph and page 142, last paragraph) as pertaining to claims 1, 5-7, 9, and 10.

Rees also teaches said beta-agonist as salmeterol or formoterol (page 139) as pertaining to claims 5-7.

***Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)***

Rees does not teach glycopyrronium bromide as said anticholinergic as claimed in claim 1. This deficiency in Rees is cured by Baichwal et al. Baichwal et al. teach

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inhalation formulations comprising glycopyrrolate as an anticholinergic and salmeterol as a bronchodilator (col. 10, lines 1-46).

Rees also does not teach said formulations produced with a carrier material as claimed in claim 10. This deficiency in Rees is cured by Baichwal et al. Baichwal et al. teach inhalable formulations comprising carrier materials (col. 5, lines 54-59).

***Finding of Prima Facie Obviousness Rational and Motivation***

***(MPEP §2142-2143)***

Regarding claims 1, 5-7, 9, and 10, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Rees with glycopyrrolate as taught by Baichwal et al. in order to produce the invention of instant claims 1, 5-7, 9, and 10.

One of ordinary skill in the art would have been motivated to do this because Rees and Baichwal et al. both teach to inhalable formulations comprising anticholinergics and bronchodilators and Baichwal et al. teach specific compounds which may be utilized. Therefore it would have been obvious to utilize the glycopyrrolate of Baichwal et al., in the formulations of Rees in order to produce an inhalable formulation with known components.

Regarding claim 10, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Rees with a carrier material as taught by Baichwal et al. in order to produce the invention of instant claim 10.

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One of ordinary skill in the art would have been motivated to do this because Rees and Baichwal et al. both teach inhalable formulations and Baichwal et al. teach that said formulations commonly comprise carrier materials. Therefore it would have been obvious to utilize the carriers of Baichwal et al., in the formulations of Rees in order to produce an inhalable formulation with known components.

Regarding the process of claim 10, Baichwal et al. teach compositions comprising all of said components and said components were inherently mixed together to form said formulations.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**4. Claims 1, 5-7, 9, and 10 are rejected under 35 U.S.C. 103(a)** as being unpatentable over “Chronic obstructive pulmonary disease: new opportunities for drug development” to Barnes, in view of US Patent 5,612,053 to Baichwal et al.

#### ***Applicant Claims***

Applicant claims are delineated above and incorporated herein.

#### ***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

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Barnes teaches inhalable formulations comprising either salmeterol or formoterol and anticholinergics (page 2, right column) as pertaining to claims 1, 5-7, 9, and 10.

***Ascertainment of the Difference between Scope the Prior Art and the Claims  
(MPEP §2141.012)***

Barnes does not teach glycopyrronium bromide as said anticholinergic as claimed in claim 1. This deficiency in Barnes is cured by Baichwal et al. Baichwal et al. teach inhalation formulations comprising glycopyrrolate as an anticholinergic and salmeterol as a bronchodilator (col. 10, lines 1-46).

Barnes also does not teach said formulations produced with a carrier material as claimed in claim 10. This deficiency in Barnes is cured by Baichwal et al. Baichwal et al. teach inhalable formulations comprising carrier materials (col. 5, lines 54-59).

***Finding of Prima Facie Obviousness Rational and Motivation  
(MPEP §2142-2143)***

Regarding claims 1, 5-7, 9, and 10, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Barnes with glycopyrrolate as taught by Baichwal et al. in order to produce the invention of instant claims 1, 5-7, 9, and 10.

One of ordinary skill in the art would have been motivated to do this because Barnes and Baichwal et al. both teach to inhalable formulations comprising anticholinergics and bronchodilators and Baichwal et al. teach specific compounds

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which may be utilized. Therefore it would have been obvious to utilize the glycopyrrolate of Baichwal et al., in the formulations of Barnes in order to produce an inhalable formulation with known components.

Regarding claim 10, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Barnes with a carrier material as taught by Baichwal et al. in order to produce the invention of instant claim 10.

One of ordinary skill in the art would have been motivated to do this because Barnes and Baichwal et al. both teach inhalable formulations and Baichwal et al. teach that said formulations commonly comprise carrier materials. Therefore it would have been obvious to utilize the carriers of Baichwal et al., in the formulations of Barnes in order to produce an inhalable formulation with known components.

Regarding the process of claim 10, Baichwal et al. teach compositions comprising all of said components and said components were inherently mixed together to form said formulations.

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From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**5. Claims 1, 5-7, 9, and 10 are rejected under 35 U.S.C. 103(a)** as being unpatentable over US Patent 6,481,435 to Hochrainer et al. in view of US Patent 5,612,053 to Baichwal et al.

#### ***Applicant Claims***

Applicant claims are delineated above and incorporated herein.

#### ***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

Hochrainer et al. teach inhalable formulations comprising betamimetics such as salmeterol and formoterol and anticholinergics (col. 5) as pertaining to claims 1, 5-7, 9, and 10.

Hochrainer et al. also teach carriers and adjuvants (col. 6, line 53 to col. 7, line 38), as pertaining to claim 10.

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***Ascertainment of the Difference between Scope the Prior Art and the Claims  
(MPEP §2141.012)***

Hochrainer et al. do not teach glycopyrronium bromide as said anticholinergic as claimed in claim 1. This deficiency in Hochrainer et al. is cured by Baichwal et al. Baichwal et al. teach inhalation formulations comprising glycopyrrolate as an anticholinergic and salmeterol as a bronchodilator (col. 10, lines 1-46).

***Finding of Prima Facie Obviousness Rational and Motivation  
(MPEP §2142-2143)***

Regarding claims 1, 5-7, 9, and 10, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Hochrainer et al. with glycopyrrolate as taught by Baichwal et al. in order to produce the invention of instant claims 1, 5-7, 9, and 10.

One of ordinary skill in the art would have been motivated to do this because Hochrainer et al. and Baichwal et al. both teach to inhalable formulations comprising anticholinergics and bronchodilators and Baichwal et al. teach specific compounds which may be utilized. Therefore it would have been obvious to utilize the glycopyrrolate of Baichwal et al., in the formulations of Hochrainer et al. in order to produce an inhalable formulation with known components.

Regarding the process of claim 10, both Hochrainer et al. and Baichwal et al. teach compositions comprising all of said components and said components were inherently mixed together to form said formulations.

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From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Response to Arguments***

Applicant's arguments with respect to all claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Claims 1, 5-7, 9, and 10 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not



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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUKE E. KARPINSKI whose telephone number is (571)270-3501. The examiner can normally be reached on Monday Friday 9-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LEK

*/Mina Haghighatian/*  
Primary Examiner, Art Unit 1616